Practitioner's Docket No. 20518/14 (M-1096)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yerlikaya et al.

Appl. No.:	09/942,334	Art Unit:	2859
Filed:	August 28, 2001	Examiner:	Mirellys Jagan
For:	TEMPERATURE PROBE ADAPTER		

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ATTENTION: Board of Patent Appeals and Interferences

APPELLANTS' BRIEF (37 C.F.R. 1.192)
[filed in triplicate]

- This brief is in furtherance of the Notice of Appeal, filed in this case on September 15, 2004 and received by the USPTO on September 20, 2004.
- The fees required under § 1.17(c), and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.
- This brief is transmitted in triplicate. (37 C.F.R. 1.192(a))
- This brief contains the following items under the following headings, and in the order set forth below (37 C.F.R. 1.192(c)):

I. REAL PARTIES IN INTEREST (37 C.F.R. 1.192(c)(1))

The real party in interest in this appeal is Sherwood Services AG, having a principal office in Bahnhofstrasse, Switzerland as the assignee of record on the original filing date of the application.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. 1.192(c)(2))

There are no other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS (37 C.F.R. 1.192(c)(3))

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: 1-28.

B. STATUS OF ALL THE CLAIMS IN APPLICATION

1. Claims canceled: None;
2. Claims withdrawn from consideration but not canceled: NONE;
3. Claims pending: 1-28;
4. Claims allowed: NONE;
5. Claims rejected: 1-28.

C. CLAIMS ON APPEAL

The claims on appeal are: 1-28.

IV. STATUS OF AMENDMENTS (37 C.F.R. 1.192(c)(4))

On August 17, 2004, claim amendments were submitted in response to the Final Rejection mailed March 17, 2004 and a Telephonic Interview between Examiner Mirellys Jagan, Supervisory Patent Examiner Diego Gutierrez and Applicants' attorney, Joseph P. Quinn. The amendments were entered as indicated by the Examiner in an Advisory Action dated September 10, 2004. The claims stand as last presented in the August 17, 2004 Amendment and as reproduced in the Appendix below.

V. SUMMARY OF INVENTION (37 C.F.R. 1.192(c)(5))

Electronic thermometers have been widely used for rapid and accurate measurements of body temperature. In digital type electronic thermometers which are commonly known, a temperature sensing probe provides an electrical signal representative of the probe temperature to a temperature calculating unit via an electrical cable. The electrical signal is converted by the temperature calculating unit into an equivalent temperature output signal. The temperature calculating unit typically provides output to a digital display which provides a digital representation of the calculated temperature reading.

Older analog type electronic thermometers known in the art use the electrical signal communicated from a temperature probe to directly drive a display needle. These older type thermometers need not perform a temperature calculation.

A temperature sensing probe is typically positioned orally, rectally, or under a patients arm position to measure a patient's temperature. Disposable probe covers are typically used to prevent the probe from being contaminated with microbes from the measured subject. Before each measurement, a disposable plastic probe cover is placed over the temperature probe. The probe cover is then disposed after each temperature reading and a new probe cover is used for

each subsequent measurement. When not in use, the temperature sensitive probe is stored in a chamber in the temperature calculating unit housing to minimize probe damage and probe contamination.

In typical use, electronic thermometers are susceptible to at least three major sources of contamination. First, when these thermometers are employed using the same temperature sensitive probes for oral, rectal and axillary temperature measurements, cross-contamination may result from use of a single probe for each type of measurement even though disposable plastic probe covers are used for each measurement. This is true because probe covers are imperfect and do not necessarily protect an engine probe from contact with microbes. In such cases, rectal or axillary contaminants on the probe may be passed orally to the same and/or other patients.

The probe storage chamber is a second potential source of contamination. When probes are stored in a single chamber in the temperature calculating unit housing, the single probe storage chamber can become contaminated and cause the spread of contamination to other probes stored therein. Contaminants on the probe from rectal or axillary use may be passed orally to the same and/or other patients.

The third source of contamination involves the disposable probe covers. In certain commonly used electronic thermometers, a probe cover is installed by inserting the probe into a box of unused disposable probe covers before each use. When temperature probes of an electronic thermometers share a common source of probe covers, probes used for taking rectal, oral and axillary temperatures are repeatedly inserted into the same source of probe covers. Contaminated temperature probes spread contamination to other unused probe covers and can pass the contaminants to the same patient and/or other patients.

Universal color codes which have been adopted by medical facilities require the use of red probes for rectal, temperature measurements and blue probes for oral and axillary

temperature measurements. This color coding system allows a healthcare practitioner to identify the proper probe to be used for each temperature reading thereby reducing the potential for cross-contamination.

The use of a separate thermometer having a blue probe for oral/axillary temperature measurements and a thermometer having a red probe for rectal temperature measurements reduces the first source of contamination described hereinbefore but is costly and inefficient. Thermometers having interchangeable probes have been developed to provide a less expensive means of avoiding cross contamination. These thermometers do not protect against cross contamination when used with a thermometer having probe storage chambers and/or probe cover storage chambers where contaminants can reside because contaminants from the probe storage chamber and/or probe cover storage chambers can be passed between interchangeable probes.

Interchangeable probes have also been found to provide inaccurate measurements because the electrical parameters of each probe are unique and vary slightly within the tolerance range of sensors in the probe.

The claimed invention solves the problems of cross contamination by providing an electronic thermometer with a removable module having a temperature probe storage chamber and a probe cover storage chamber. The module is removably connectable to a temperature calculating unit. The module also includes a memory which stores calibration information. Accordingly, the problem of inaccurate measurements provided by heretofore known interchangeable probes is solved by storing calibration parameters of a removable probe in memory residing with the removable module.

Calibration information such as the resistance of the probe thermisters at corresponding calibration temperatures and probe identification data, i.e., serial numbers or probe type identifiers, is stored in the embedded memory component in the probe assembly. The electronic

components of the base (temperature calculating) unit can read data from the memory component and compensate for variation in the probe thermisters according to the stored calibration information. The additional identifying information can be used by the thermometer base electronics to perform any number of functions. Such functions could include the use of separate algorithms for calculating a predicted temperature depending on the type of probe used.

The disclosed electronic thermometer provides improved performance and accuracy over prior art electronic thermometers. Embodiments of the invention feature more than one temperature sensor in a temperature probe for improved accuracy.

Disclosed embodiments provide storage of all calibration parameters of the temperature sensors including calibration data for at least two different reference temperatures. This reduces linearity errors and improves a regression process used in the temperature calculation algorithm.

The disclosed embodiments allow the reduction or elimination of calibration costs during manufacturing of the temperature probe. Manufacturing costs are further reduced by mounting the memory component on the same small circuit board that acts as an interface between the probe cable conductors and their connector pins. Embodiments of the invention feature encapsulation of the memory components in a strain relief portion of the probe cable to prevent fluid incursion into the electronic components and probe cable.

The thermometer as claimed in independent claims 1, 2, 6, 22, and 28 and the method of preventing contamination as claimed in independent claim 5 each include the essential elements of a removable module having a probe chamber, a probe cover chamber, and a memory removably matable to a temperature calculating unit. These essential elements clearly distinguish over the prior art, provide substantial advantages over the prior art and solve problems in the art that have been heretofore unsolved.

VI. ISSUES (37 C.F.R. 1.192(c)(6))

The issue under appeal is whether the Examiner's rejection of claims 1 - 28 under 35 U.S.C. § 103(a) as being unpatentable over McBean, Sr. (USP 5,347,476) in view of Eberly, Jr. (USP 3,681,991) is proper.

Appellant appeals the rejections as improper and requests that the claims be allowed and the case passed to issue.

VII. GROUPING OF CLAIMS (37 C.F.R. 1.192(c)(7))

Claim 1 and its dependent claims 3-4, 7-21 and 23-24 are separately patentable.

Claim 2 is separately patentable.

Claim 5 and its dependent claim 15 are separately patentable.

Claim 6 is separately patentable.

Claim 22 and its dependent claims 26-27 are separately patentable.

Claim 28 is separately patentable.

VIII. ARGUMENTS: REJECTION OF CLAIMS 1 – 28 UNDER 35 U.S.C. 103(a) (37 C.F.R. 1.192(c)(8)(iv))

In the Final Office Action dated March 17, 2004, The Examiner rejected claims 1-28 as being unpatentable over U.S. Patent No. 5,347,476 to McBean, Sr. (hereinafter referred to as "McBean") in view of U.S. Patent No. 3,681,991 to Eberly, Jr. (hereinafter referred to as "Eberly").

The Examiner indicated that "McBean discloses an electronic thermometer comprising: a removable module (20)... (having a) temperature sensing assembly formed by a temperature sensor(22)connected to a memory chip (EEPROM 24) that stores calibration information and module-specific algorithm parameters, and a cable assembly having a connecting portion with mating terminals for electrically connecting to a temperature calculating unit, and a temperature calculating unit..." (Page 15, line 17 – page 16, line 4).

The Examiner admitted that "McBean does not disclose the temperature sensor of the removable module being in a probe connected to the removable module, wherein the removable module is capable of storing the temperature sensitive probe and a supply of disposable probe covers, the memory storing 'probe identifying' information or 'probe specific' algorithm parameters and the temperature sensing assembly being a 'probe assembly." (Page 16, lines 14 – 18".

The Examiner indicated that "Eberly discloses an electronic thermometer comprising a hand-held module(26) that includes a temperature sensor in a probe (34) that is connected to the module by a cable. ... The module (26) stores the temperature sensitive probe in a chamber (32) in order to protect the probe when it is not being used. Eberly also teaches providing the module with a chamber (86 or 88) for housing a supply of disposable probe covers in order to have clean probe covers readily available to a person using the module when taking temperature measurements. The probe cover supply storage chamber is permanently attached to the probe storage chamber." (Page 16, line 19 – page 17, line 5).

A) Examiner's Mischaracterization of Eberly

Contrary to the Examiner's characterization of Eberly quoted directly above, nothing in Eberly teaches or suggests a module.

The Examiner erroneously indicated that Eberly discloses an electronic thermometer comprising "a hand-held module (26)." It is significant to note that numeral 26 in Eberly is not used to identify a module but is actually used to identify a casing of a conventional DC meter. (Col. 3, lines 50-56). Furthermore, nothing in Eberly teaches or suggests that the thermometer described therein is "hand-held".

The Examiner's repeated misuse of the term "module" with respect to Eberly is therefore misleading. It should be understood that, contrary to the Examiner's characterization, Eberly does not disclose: a probe connected to the module by a cable; a module that stores a temperature sensitive probe in a chamber; or providing the module with a chamber for housing a supply of disposable probe covers.

In the Advisory Action dated September 10, 2004, the Examiner indicated that "Applicant's arguments that Eberly does not teach or suggest the removable module of the present invention are not persuasive since the rejections are not based on replacing the removable module of McBean with the module of Eberly. The rejections are based on modifying the removable module of McBean by adding chambers to the module as taught by Eberly."

It is nonetheless misleading for the Examiner to use the term "module" so loosely when the term has specific meaning in the present application. By indicating that Eberly teaches modules, the Examiner improperly implies that Eberly includes this claimed element and thereby implies an enhanced teaching or suggestion to combine with McBean. Such a teaching or suggestion can not be found anywhere in Eberly.

B) Hindsight/Lack of Motivation to Combine

In the Final Office Action, the Examiner indicated "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the removable module disclosed by McBean by adding a chamber in the module for storing the probe and a chamber in the module for storing a supply of disposable probe covers as taught by Eberly in order to store the probe and protect it when it is not being used, and allow a person using the module to have clean probe covers readily available when using the module to take temperature measurements" (page 17, lines 12-17). Appellants respectfully submit that the Examiner has not identified a proper motivation to combine provided by the references or knowledge of persons skilled in the art.

Appellants submit that the Examiner used improper hindsight to find a motivation to combine the teachings of Eberly and McBean. The desire to have clean probe covers readily available alone would not motivate a combination of Eberly and McBean to result in the claimed invention. One who is simply motivated to have clean probe covers readily available could do so in a number of ways that do not involve placing a probe chamber, probe cover chambers and a memory in a single module as claimed. For example, having a supply of clean probe covers in the thermometer housing case, (as taught by Eberly), rather than in a removable a module would serve the same purpose.

It is well settled that claims are unpatentable if the differences between them and the prior are "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); see Graham v. John Deere Co., 383 U.S. 1, 14, 148 USPQ 459, 465 (1966).

The phrase "at the time the invention was made" guards against entry into the "tempting but forbidden zone of hindsight when analyzing the patentability of claims pursuant to that section." In re Dembiczak, 50 USPQ2d 1614, 1616 (Fed. Cir. 1999) citing Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 873, 228 USPQ 90, 98 (Fed. Cir. 1985), overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 46 USPQ2d 1097 (Fed. Cir. 1998).

The Court of Appeals for Federal Circuit has held that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirements for a showing of the teaching or motivation to combine prior art references." Id. at 1617. Presently, the Examiner has not shown a rigorous application of the requirements for showing a motivation to combine the references.

The reason one of ordinary skill in the art would have motivated to select the references and combine them must be specifically identified. Id. citing In re Fritch, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). Presently, the Examiner has not provided any motivation to select the particular references.

"Evidence of teaching or suggestion is "essential" to avoid hindsight." Id. citing In re Fine, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of Hindsight." Id. The Examiner's stated motivation to combine: "in order to store the probe and protect it when it was not being used, and allow a person using the module to have clean probe covers readily available when using the module to take temperature measurements" (page 17, lines 15-16) is such a broad

conclusory statement which uses the inventors' disclosure as a blueprint for piecing together the prior art to defeat patentability.

The Court of Appeals for the Federal Circuit has held that even though "evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or in some cases, from the nature of the problem to be solved, ... the suggestion more often than not comes from the teachings of the pertinent references. ... The range of sources available, however, does not diminish the requirement for actual evidence, that is, the showing must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." Id.

C) Combination of McBean and Eberly Does Not Result In Clamed Invention

Even if motivation existed to combine Eberly with McBean for the purpose of providing readily available probe covers, the resulting structure would not locate probe cover chambers in the removable module, but would instead locate them in the temperature calculating unit/housing as the chambers are located in the housing of Eberly. This combination would serve the purpose identified by the Examiner of providing readily available probe covers without requiring each and every element of the claimed invention. Eberly also teaches the use of a plurality of probe cover chambers and a plurality of probes (Figs. 1, 9). A combinations of Eberly and McBean might therefore include a plurality of probe chambers in the housing. Such a combination would invite the contamination problems that the present invention solves, and therefore teaches away from the present invention.

Since persons having ordinary skill in the art would not be motivated to combine Eberly with McBean in a way that would result in the invention as claimed, the Examiner has not made a case of prima facie obviousness under 35 U.S.C. 103(a). The Examiner's rejections are improper and should be overturned.

In view of these arguments, Appellant respectfully requests the rejections of all of the claims pending in the present application be overturned.

Respectfully Submitted,

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IX. APPENDIX: CLAIMS INVOLVED IN THE APPEAL (37 C.F.R. 1.192(c)(9))

The text of the claims involved in the appeal are:

1. An electronic thermometer comprising:

a removable module having a memory , a temperature probe storage chamber and a probe cover storage chamber, wherein said memory stores calibration information; and

a temperature calculating unit removably mating to said removable module.

2. An electronic thermometer comprising:

a removable module having a memory, a temperature probe storage chamber and a probe cover storage chamber, wherein said memory stores temperature probe identifying information; and

a temperature calculating unit removably mating to said removable module.

3. An electronic thermometer according to claim 1 wherein said memory is capable of electrical communication with said temperature calculating unit when said removable module is installed to said temperature calculating unit.

4. An electronic thermometer according to claim 1 wherein said calibration information includes at least two calibration reference point parameters wherein each of said at least two calibration reference point parameters are taken at different temperatures.

5. A method of preventing contamination of a removable temperature probe in an electronic thermometer comprising the steps of:

storing probe-identifying information in a memory chip;

connecting said memory chip to said temperature probe;

storing said temperature probe in a removable module;

storing a supply of clean disposable temperature probe covers in said removable module;

removably connecting said removable module to a temperature calculating unit; and

communicating said probe-identifying information from said memory chip to said temperature calculating unit.

6. An electronic thermometer comprising:

at least one removable module including a temperature probe and means for storing a supply of clean probe covers;

at least one temperature calculating unit capable of mating to said at least one removable module;

means for storing probe identifying information within said at least one removable module; and

means for communicating said probe identifying information between said means for storing and said temperature calculating unit.

7. An electronic thermometer according to claim 1 wherein said memory includes an EEPROM.

8. An electronic thermometer according to claim 1 wherein said memory is a 256 bit, 1-Wire, parasite-power, EEPROM.

9. An electronic thermometer according to claim 1 wherein said removable module includes means for storing probe-specific algorithm parameters.

10. An electronic thermometer according to claim 1 wherein said memory is encapsulated within said removable module.

11. An electronic thermometer according to claim 1 wherein said memory is incorporated in a probe assembly of said removable module.

12. An electronic thermometer according to claim 11 wherein connections to said memory are protected from fluid incursion.

13. An electronic thermometer according to claim 11 wherein said memory is disposed in a connector portion of a probe cable assembly of said removable module.

14. An electronic thermometer according to claim 1 wherein said removable module includes a probe assembly incorporated therewith, said probe assembly comprising a temperature probe, an electrical cable and a first connector component, and wherein said first connector component includes fluid resistant mating terminals providing electrical connections to said probe and said memory wherein said memory is incorporated within said probe assembly.

15. An electronic thermometer according to claim 14 wherein said memory is overmolded within said first connector component.

16. An electronic thermometer according to claim 14 wherein said temperature calculating unit includes a header assembly incorporated therewith, said header assembly including header terminals in electrical connection with a microprocessor system, said header assembly matable with said first connector component of said removable module.

17. An electronic thermometer according to claim 16 wherein said header assembly is fluid resistant, said header assembly preventing fluid incursion to said microprocessor system.

18. An electronic thermometer according to claim 14 wherein said probe includes at least one thermistor electrically connected with said terminals, and wherein said calibration information includes resistance values of each of said at least one thermistor, said resistance values corresponding to at least two different reference temperatures.

19. An electronic thermometer according to claim 14 wherein said memory stores temperature probe identifying information.

20. An electronic thermometer according to claim 19 wherein said probe identifying information includes a unique identification number associated with said temperature probe.

21. An electronic thermometer according to claim 20 wherein said unique identification number is a pre-programmed and validated EEPROM registration number.

22. An electronic thermometer comprising:

a temperature calculating unit; and

a removable module including storage for a supply of clean probe covers and a probe assembly incorporated therewith, said probe assembly comprising a temperature probe, a cable having a first end connected to said temperature probe and a second end connected to a connector portion; wherein said connector portion includes fluid resistant mating terminals providing electrical connections to said probe and, a memory wherein said memory is incorporated within said probe assembly;

wherein said memory stores temperature probe identifying data and temperature probe calibration data, said temperature probe identifying data including a unique identification number associated with said temperature probe;

wherein said temperature probe includes at least one thermistor electrically connected with said mating terminals and wherein said temperature probe calibration information includes resistance values of each of said at least one thermistor, said resistance values corresponding to at least two different reference temperatures; and

wherein said temperature calculating unit includes a header assembly incorporated therewith, said header assembly including header terminals in electrical connection with a microprocessor system, said header assembly matable with said connector portion of said removable module, wherein said header assembly is fluid resistant, said header assembly preventing fluid incursion to said microprocessor system.

23. An electronic thermometer according to claim 1 wherein said temperature probe storage chamber_prevents storage of said temperature probe while a probe cover is installed on said temperature probe.

24. An electronic thermometer according to claim 1 wherein said removable module comprises an at least partially transparent housing for viewing said supply of disposable probe covers.

25. The method according to claim 5 further comprising the step of providing means to store said temperature probe within said module for preventing storage of said temperature probe while a probe cover is installed thereon.

26. The thermometer according to claim 22 wherein said removable module comprises an isolation chamber that prevents storage of said temperature probe while a probe cover is installed thereon.

27. The thermometer according to claim 22 wherein said removable module comprises an at least partially transparent housing for viewing said supply of disposable probe covers.

28. An electronic thermometer comprising:

a removable module comprising a memory storing probe identification and calibration information,

said removable module comprising a probe storage chamber and probe cover supply storage chamber permanently attached to said probe storage chamber; and

a temperature calculating unit removably mating to said removable module.